REMARKS

Summary of Office Action

As an initial matter, Applicants note that the Examiner has failed to acknowledge the receipt of a certified copy of the priority document, German Application No. 101 21 471.5, in the Office Action Summary. Accordingly, Applicants respectfully request that the receipt of a certified copy of the priority document be acknowledged in the Office Action Summary in the next communication from the Patent and Trademark Office.

Claims 56-58 and 68-72 filed in response to the previous Office Action are withdrawn from consideration.

Applicants note with appreciation that the rejection of claim 36 under 35 U.S.C. § 112, first paragraph, the rejection of claims 27, 28, 31, 36 and 39 under 35 U.S.C. § 102(b) over U.S. Patent No. 4,839,174, and all rejections under 35 U.S.C. § 103(a) based on U.S. Patent No. 4,839,174 have been withdrawn.

Claim 28 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 27, 28, 31, 36 and 37 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 0 212 681 (hereafter "EP'681").

Claim 29 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of Ganster et al., U.S. Patent No. 6,191,216 (hereafter "GANSTER").

Claim 32 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of Hobson et al., U.S. Patent No. 6,399,092 (hereafter "HOBSON").

Claims 33, 35, 38, 39, 62 and 67 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of U.S. Patent No. 5,866,157 to Higo et al. (hereafter "HIGO").

Claims 33 and 34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of U.S. Patent No. 6,630,442 to Hersh (hereafter "HERSH").

Claims 33, 35, 64 and 67 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of EP 1 059 032 (hereafter "EP'032").

Claim 59 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over "US'861" in view of Muchin et al., U.S. Patent No. 6,183,770 (hereafter "MUCHIN").

Claims 62-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of Shudo et al., U.S. Patent No. 6,698,162 (hereafter "SHUDO").

Claims 60, 61, 65 and 66 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of Toppo, U.S. Patent No. 5,985,860 (hereafter "TOPPO").

Response to Office Action

Withdrawal of the finality of the present Office Action and reconsideration and withdrawal of the rejections of record are respectfully requested in view of the following remarks.

Response to Restriction and Request to Withdraw Finality of Office Action

Claims 56-58 and 68-72 filed in response to the previous Office Action are withdrawn from consideration. In this regard, the Office alleges that claims 56-58 and 68-72 are directed to an invention that is independent and distinct from the invention originally claimed in claims 27-32, 34-

39 and 56-67 (invention I). The Office further alleges that claims 56-58 "are directed to method of making the adhesive patch that have been previously withdrawn", that claims 68-71 "do not require the specific active agent required by invention I" and that claim 72 "does not require the specific polyurethane required by invention I".

Applicants respectfully submit that contrary to what is alleged in the present Office Action, claims 56-58 are not method claims, but product(-by-process) claims and as such are directed to the same invention as, e.g., claim 27 (from which they are dependent, directly or indirectly).

Applicants further submit that present independent claim 27, for example, recites an "active ingredient", i.e., not a "specific active agent", wherefore there is no difference in this regard between independent claim 27 (considered by the Examiner) and, e.g., independent claim 68 (withdrawn from consideration). In fact, independent claim 68 corresponds generally to a combination of claims 27, 29 and 31, all of which have been considered by the Examiner.

It also is submitted that contrary to what is alleged in the present Office Action, invention I does not require a "specific polyurethane". In this regard, present independent claim 27 may, for example, by referred to. It is noted that both claim 27 and claim 72 recite merely an "absorbent, self-adhesive polyurethane matrix". In fact, present claim 72 corresponds generally to a combination of claims 27, 34, 36, 60, 61 and 63, all of which have been considered by the Examiner.

In view of the foregoing, it is submitted that Applicants are entitled to an examination of claims 56-58 and 68-72 in the present application. Accordingly, Applicants respectfully request that the finality of the present Office Action be withdrawn and that in the next Office Action claims 56-58 and 68-72 be examined on the merits.

Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claim 28 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection again alleges that the rejected claim has introduced new matter that allegedly is not described in the specification as originally filed. In this regard, the rejection alleges that in Example 7 and Table 2 "applicants disclosed strong bond between the adhesive and a steel after application of polyurethane and not after application of the active ingredient" (page 4, last paragraph of Office Action)

Applicants again respectfully traverse this rejection. In this regard, Applicants direct the Examiner's attention to the second row of Table 2 at page 33 of the present specification which lists the theoretical amount of applied active ingredient (IBU = ibuprofen) after 3 and 4 coats, respectively. The results in Table 2 (third row) also show that the bond strength values of the uncoated sample and the two coated samples are essentially the same.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the response to the previous Office Action, the Examiner has failed to establish that claim 28 does not comply with the written description requirement, wherefore withdrawal of the rejection of claim 28 under 35 U.S.C. § 112, first paragraph, is again respectfully requested.

Response to Rejection under 35 U.S.C. § 102(b) over EP'681

Claims 27, 28, 31, 36 and 37 are again rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP'681. In this regard, the rejection alleges, *inter alia*, that "EP'681 disclosed polyurethane matrix made from polyetherpolyols and hexamethylene diisocyanate (second full

paragraph of col. 7), therefore, the polyurethane disclosed by the reference is self-adhesive since compounds and their properties are inseparable". The rejection also alleges that "the additional adhesive layer disclosed by the reference is optional, implementing [*sic*] that the matrix itself is adhesive in absence if the skin contact adhesive." Page 6, second paragraph of present Office Action.

Applicants respectfully traverse this rejection again. Specifically, Applicants maintain that the drug releasing member of the drug release system of EP'681 is not self-adhesive. This becomes clear from reading the passage from col. 8, line 49 to col. 9, line 11 of EP'681 which states (emphases added):

> A thin continuous layer of adhesive 14 is applied to the fully cured and prepared substrate layer, with or without the fabric reinforcement, in a conventional manner. Any pressure-sensitive adhesive conventionally used for wound dressings or bandages may be spread over the layer, e.g. a polyacrylate adhesive or a polyvinylethyl ether blend adhesive.
>
> The drug releasing member 16, as described above, is then applied to the adhesive 14 by setting it thereon.
>
> A second layer of adhesive 18 may optionally be applied to the exposed side of the drug releasing member 16. As well as making the medical patch ready for application to a person, this second adhesive layer could be used for debridement on burn patients, in which removal of the medical patch removes the dead burned skin and cleans the wound.

Accordingly, contrary to what is alleged in the present Office Action, the (first) adhesive layer is not optional in EP'681. What is optional is the second adhesive layer which may be applied directly on the surface of the drug releasing member which is to come into contact with the skin. This optional second layer may be of advantage, for example, if removal of dead skin concurrently with the removal of the drug releasing member from the skin is desired. At any rate, if the drug releasing member of EP'681 were self-adhesive, providing the second adhesive layer directly on the drug releasing layer would not be necessary even in situations were the removal of dead skin is

desired, which is yet another clear indication that the polyurethane matrix of EP'681 is not adhesive by itself.

Applicants also point out that in addition to a diisocyanate (such as, e.g., hexamethylene diisocyanate) and a glycol having a molecular weight of 500-5000 the starting materials for the radiation-curable polyurethane oligomers of EP'681 further comprise an acrylyl chain terminator having a molecular weight of 40-200 (see, e.g. claim 1 of EP'681). Apparently, the acrylyl component is necessary for providing radiation curability. This may be one of the reasons why the polyurethanes made from the radiation-curable oligomers are not self-adhesive.

At any rate, even without the presence of the acrylyl chain terminator there would be no basis for the assumption that the polyurethanes of EP'681 are necessarily self-adhesive. It is pointed out again that the Examiner has not provided any written or other evidence whatsoever which would support an allegation that a polyurethane which is made of, e.g., hexamethylene diisocyanate and a glycol having a molecular weight of 500-5000 is necessarily self-adhesive. In this regard, the Examiner is reminded that matter is "inherent" if the extrinsic evidence makes it clear that the matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002); *In re Crish*, 393 F.3d 1253, 1258-59 (Fed. Cir. 2004). Inherency, however, cannot arise from probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. To the contrary, a certain thing must result from a given set of circumstances to be inherent. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the response to the previous Office Action, the rejection of claims 27, 28, 31, 36 and 37 under 35 U.S.C. § 102(b) over EP'681 is clearly unwarranted, wherefore withdrawal thereof is again respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681 in View of GANSTER

Claim 29 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of GANSTER. The rejection again essentially asserts that GANSTER discloses a polyurethane of the type recited in present claim 29 and that it would allegedly have been obvious for one of ordinary skill in the art to replace the polyurethanes used by EP'681 by the polyurethanes disclosed in GANSTER.

Applicants again respectfully disagree with the Examiner in this regard. Specifically, according to EP'681 not a polyurethane, but a polyurethane-forming oligomer that can be cured, without releasing heat, by exposing it to actinic radiation must be employed (see, e.g., abstract and col. 4, lines 11-15, of EP'681). Specifically, EP'681 states (col. 4, lines 11-23; emphases added):

> The ability to cure without release of heat is a particularly important characteristic of the oligomer because many drugs are heat labile and the drug embodied in this oligomer must remain active after curing to the polymer. The cured oligomer or polyurethane must also be capable of releasing the drug in a controlled, sustained manner so that it elutes out at a therapeutically beneficial rate. The oligomer must not contain water or solvents, which hinder the effectiveness of many drugs and it must cure to a completely cured polymer, leaving no sites available to react with the drug. The cured oligomer or polyurethane should be flexible so that it can be made to conform to the site of the contact to the wearer. In addition, when the system contacts the skin of the wearer, it must breath, i.e. be oxygen and water vapor permeable, and be biocompatible.

Applicants are unable to see why one of ordinary skill of the art would have assumed that the polyurethane of GANSTER can satisfy all of the above requirements which are set forth in EP'681 and would have been motivated to replace the polyurethane of EP'681 as a drug releasing matrix by the polyurethane of GANSTER, and neither does the present Office Action offer any explanation in this regard.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in response to the previous Office Action, GANSTER fails to render obvious the subject matter of claim 29, wherefore withdrawal of the rejection of claim 29 under 35 U.S.C. § 103(a) over EP'681 in view of GANSTER is warranted and again respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681 in View of HOBSON

Claim 32 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of HOBSON. The rejection again alleges that HOBSON teaches a wound dressing containing a superabsorbent polymer and an active ingredient that when applied to the skin absorbs fluid and slowly releases the active agent into the skin, wherefore it would allegedly have been obvious to one of ordinary skill in the art to provide a drug releasing system as disclosed in EP'681 and to further add superabsorbent to the drug containing matrix.

Applicants respectfully traverse this rejection as well. Applicants again direct the Examiner's attention to col. 5, lines 28-53 of EP'681 where it is stated (emphases added):

> ... Stated another way, any drug that functions in its intended manner after exposure to actinic radiation is operable in the present drug release system. For reasons which follow, the drug also must be water soluble.
>
> The cured polyurethane product or drug releasing member is crystal clear, biocompatible,

soft and elastomeric and serves to release the incorporated drug in a controlled, sustained manner while protecting the portion of the incorporated drug yet to be released. The cured polyurethane is a solid and contains the selected drug dispersed throughout the polyurethane. Since the polyurethane of the drug releasing member is somewhat hydrophilic, it absorbs water vapor evaporating from the skin of the wearer. As the water vapor permeates through the polyurethane, it condenses to water and dissolves the drug. The flow of the drug to the wearer of the medical patch proceeds in a controlled sustained manner because of the concentration differential. That is, the drug will flow out of the polyurethane where there is a high concentration of the drug and into the skin where there is a low concentration of the drug. In addition, the release is controlled by the size of the molecular pores which are formed in the polyurethane.

The above passage of EP'681 makes it clear that the presence of water is essential for the functioning of the drug delivery system disclosed therein. It also makes it clear that the drug release rate is controlled by the concentration differential of the drug and the pore size of the polyurethane. Accordingly, one of ordinary skill in the art would recognize that the presence of a superabsorbent such as, e.g., the superabsorbent of HOBSON in this system would interfere with the absorption of water by the polyurethane and the flow of the dissolved drug from the polyurethane matrix to the skin of the wearer. One of ordinary skill in the art would also recognize that the presence of a superabsorbent in the system of EP'681 would interfere with the control of the drug release by the pore size of the polyurethane. These apparent considerations would rather be a disincentive than a motivation to incorporate the superabsorbent of HOBSON into the drug releasing polyurethane matrix of EP'681.

Applicants further point out that HOBSON in no way teaches or suggests that the superabsorbent disclosed therein may be used in combination with just any polymer matrix such as, e.g., a polyurethane. On the contrary, HOBSON teaches that the superabsorbent disclosed therein is to be used in combination with two specific classes of polymeric materials, i.e., poloxamers and

polyols (see, e.g., claims 1-4 of HOBSON). Neither poloxamers nor polyols bear any structural (or other) resemblance to the polyurethanes of EP'681, which is yet another reason why one of ordinary skill in the art would not have been motivated to use the superabsorbent of HOBSON with the polyurethane of EP'681.

Applicants respectfully submit that for at least all of the foregoing reasons and the additional reasons set forth in response to the previous Office Action, the rejection of claim 32 under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of HOBSON is without merit and should be withdrawn as well.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681 in View of MUCHIN

Claim 59 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over "US'861" (it is assumed that EP'681 was intended and confirmation in this regard is respectfully requested) in view of MUCHIN. The rejection concedes that EP'681 "does not explicitly teach the application of the active ingredient on the surface of the adhesive". In this regard, the rejection alleges that MUCHIN teaches a patch for delivering agents to the skin, which patch comprises an adhesive on the lower surface of a pad and that an active agent for delivery to the skin is applied to the patch in a manner such that the deleterious effects of the adhesive on the active agent are minimized. The rejection further asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention to provide transdermal patch comprising polyurethane matrix incorporating drug as disclosed by EP'681, and add active agent on the skin contacting surface of the polyurethane matrix instead of incorporating the drug into the matrix as disclosed by US'770, motivated by the teachings

of US'770 that such a structure of the patch minimizes the deleterious effects of the adhesive on the active" (page 18, first paragraph of Office Action).

In response, Applicants submit that claim 59 recites, *inter alia*, that "the active ingredient dissolved in a solvent has been applied to the first side of the matrix and none or only a portion of the solvent has been evaporated such that at least a portion of the solvent remains in the matrix". In other words, claim 59 recites not only the application of the active ingredient dissolved in a solvent to one side of the self-adhesive polyurethane matrix, but also that none or only a portion of the solvent is evaporated so that at least a portion of the solvent remains in the matrix.

Even if one were to assume, *arguendo*, that one of ordinary skill in the art would want to apply a dissolved drug onto the surface of the cured polyurethane matrix of EP'681, it is not seen that MUCHIN teaches or suggests, *inter alia*, evaporating none or only a portion of the solvent so that at least a portion of the solvent remains in the matrix, and neither does the present Office Action offer any explanation in this regard.

It is submitted that for at least all of the foregoing reasons, the rejection of claim 59 under 35 U.S.C. § 103(a) over EP'681 in view of MUCHIN is without merit, wherefore withdrawal thereof is warranted and respectfully requested.

Response to Remaining Rejections under 35 U.S.C. § 103(a)

Dependent claims 33, 35, 38, 39, 62 and 67 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of HIGO. Dependent claims 33 and 34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of HERSH. Dependent

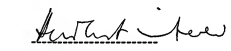
claims 33, 35, 64 and 67 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of EP'032. Dependent claims 62-65 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of SHUDO, and dependent claims 60, 61, 65 and 66 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of TOPPO.

Because it is apparent that none of HIGO, HERSH, EP'032, SHUDO and TOPPO can cure the deficiencies of EP'681 which are set forth above and in the response to the previous Office Action, Applicants refrain from commenting on the allegations with respect to HIGO, HERSH, EP'032, SHUDO and TOPPO which are contained in the present Office Action, without admitting however, that any of these allegations is meritorious. Accordingly, withdrawal of the corresponding rejections is respectfully requested as well.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
Michael SCHINK et al.



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